

## JAN 13 2005 510(K) SUMMARY

## Antares Diagnostic Ultrasound System with 4D Basic Imaging

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

**1. Submitted By:**

Siemens Medical Solutions USA, Inc.  
22010 S.E. 51st Street  
Issaquah, WA 98027-7298

**Contact Person:**

Patrick Lynch  
Regulatory Affairs

Phone: (425) 557-1825

FAX: (425) 391-9198

**Date Prepared:**

December 22, 2004

**2.****Proprietary Name:**

SONOLINE Antares™ Ultrasound System

**Common/ Usual Name:**

Diagnostic Ultrasound System with Accessories

**Classification Name:**

21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System

FR # 892.1550

Product Code 90-IYN

Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

**3. Predicate Device:**

The Antares system is multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the following products which are already cleared for US distribution with the following 510(k) clearances:

- K001400, 8/1/00, cleared as the Elegra Millennium Advanced, marketed as the Antares
- K040060, 01/28/04, cleared as SONOLINE G50/G60 S Diagnostic Ultrasound System

**4. Device Description:**

The Antares with 4D Basic Imaging is substantially equivalent to the predicates listed herein. The Antares is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PWD) Doppler Mode, Continuous (CWD) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, 3D imaging, and 4D Basic Imaging on a CRT display.

The Antares has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

**5. Intended Uses:**

The Antares ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

**6. Technological Comparison to Predicate Device:**

Antares Avant is substantially equivalent to the SONOLINE Elegra Millennium Enhanced, cleared via K001400, and the SONOLINE G50/G60 S Diagnostic Ultrasound System, cleared via K040060. All systems transmit ultrasonic energy into patients, then perform postprocessing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

**End of 510(k) Summary**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 13 2005

Siemens Medical Solutions USA, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K050034

Trade Name: SONOLINE Antares™ Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: 90 IYN, IYO, and ITX  
Dated: January 5, 2005  
Received: January 7, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOLINE Antares™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2  
CW5

C5-2 Curved Array  
CX5-2 Curved Array

VF7-3 Linear Array  
EC9-4 Curved Array  
VFX9-4 Linear Array  
VF10-5 Linear Array  
VF13-5 Linear Array  
VFX13-5 Multi-D Array  
PX4-1 Phased Array  
MPT7-4 Multiplane TEE

CH6-2 Curved Array  
PH4-1 Phased Array  
P10-4 Phased Array  
VF13-5SP Linear Array  
C5F1 Curved Array  
C7F2 Curved Array  
EV9F4 Curved Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

A handwritten signature in cursive script, reading "Nancy C. Brogdon".

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

## FDA Cleared Indications for Use Forms

510 (k) Number (if known):

Device Name:

SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative (Note 9)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign Off)

Division of Reproductive, Abdominal  
and Radiological Devices

12/22/2004

510(k) Number

K050034

Section 4.3, Page 2 of 21

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

CW2 Probe for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

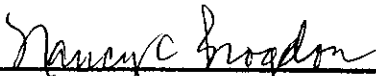
Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

CW5 Probe for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					N					
Abdominal					N					
Intraoperative (Note 9)					N					
Intraoperative Neurological										
Pediatric					N					
Small Organ (Note 1)					N					
Neonatal Cephalic					N					
Adult Cephalic					N					
Cardiac					N					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					N					
Laparoscopic										
Musculo-skeletal Conventional					N					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Nancy C. Brogdon*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034



## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

C5-2 Curved Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										


N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: CX5-2 Curved Array Transducer for use with SONOLINE Antares  
 Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

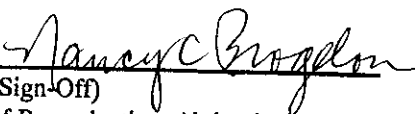
N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

VF7-3 Linear Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

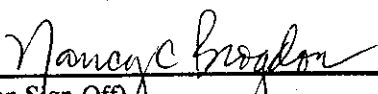
Note 5 3-Scape real-time 3D imaging

Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)
Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

EC9-4 Curved Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										


N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

VFX9-4 Linear Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

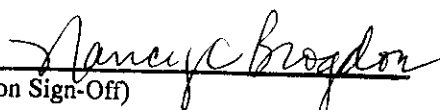
Note 5 3-Scape real-time 3D imaging

Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)
Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

VF13-5 Linear Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

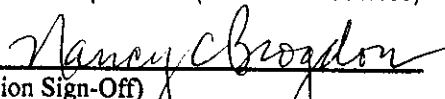
Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)
Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

VFX13-5 Multi-D Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Abdominal		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										


N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K050034



## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

PX4-1 Phased Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 6 Cadence contrast agent imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Nancy C. Brogdon*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

**MPT7-4 Multiplane TEE Transducer for use with SONOLINE Antares**

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

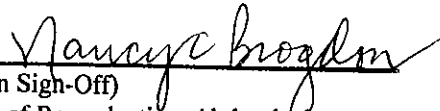
N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 6 Cadence contrast agent imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)
Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

CH6-2 Curved Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Nancy Brogdon*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

PH4-1 Phased Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Nancy Brogdon*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

P10-4 Phased Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K001400; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 6 Cadence contrast agent imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Nancy C. Brody*  
 (Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

VF13-5SP Linear Array Transducer for use with SONOLINE Antares

Indications For Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Other (specify)										

N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

**C5F1 Curved array mechanical 3D transducer for use with SONOLINE Antares**  
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

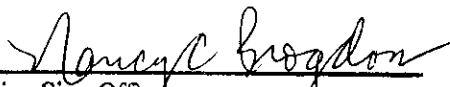
N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K050034

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

**C7F2 Curved array mechanical 3D transducer for use with SONOLINE Antares**

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Musculo-skeletal Superficial										
Other (specify)										

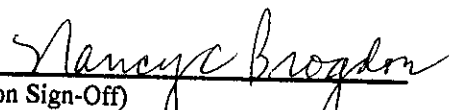
N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging  
 Note 3 SieClear multi-view spatial compounding  
 Note 4 Tissue Equalization Technology  
 Note 5 3-Scape real-time 3D imaging  
 Note 7 B&W SieScape panoramic imaging  
 Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)
Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034



## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

EV9F4 Curved Array Transducer for use with SONOLINE Antares

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

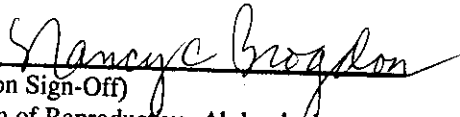
Note 5 3-Scape real-time 3D imaging

Note 7 B&amp;W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number K050034